IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
STATESVILLE DIVISION

RAMONA WINEBARGER and REX WINEBARGER,
Plaintiffs,

CASE NOS. 5:15CV57-RLV; 3:15CV211-RLV

v.
BOSTON SCIENTIFIC CORPORATION,
Defendant

MARTHA CARLSON,
Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION
Defendants

PLAINTIFFS OBJECTIONS AND COUNTER DESIGNATIONS TO DEFENDANT BOSTON SCIENTIFIC'S DEPOSITION DESIGNATIONS OF CAROLYN CORYELL, MD, TAKEN 10/17/2014

BSC Designations	Objection	Plaintiffs Counter Designation
cc101714, (Pages 12:17 to 14:19) *** 16 Q In your experience has there been a 17 higher failure rate with native tissue repairs as 18 opposed to mesh repairs for pelvic organ prolapse? 19 A Yes.	14:16-19 FRE 401, 403, 702 Foundation	
cc101714, (Pages 15:11 to 16:2) 15 11 Q My question was I was curious about 12 your experience with performing native tissue 13 repairs for repairing pelvic organ prolapse when 14 compared to using mesh. 15 MR. CASPERSON: Objection to form. 16 A I have more experience with mesh than 17 with native tissue because generally there has been	15:11-24 FRE 401, 403, 702 , Foundation	

18 less discomfort associated with the recovery period, 19 because wherever you collect the native tissue from 20 has to also heal, unless you're just tightening the 21 vagina itself. And if you're just tightening the 22 vagina itself it -- it has a higher failure rate. 23 But I cannot give you a number on that 'cause I 24 haven't calculated it. ***		
cc101714, (Page 25:3 to 25:6) 25 3 Q Generally do you feel that mesh is a 4 safe option for some women as a treatment of pelvic 5 organ prolapse? 6 A Yes.		cc101714, (Pages 21:20 to 22:15) *21* *20 Did you stop using mesh for* *21 pelvic organ prolapse repairs and for SUI at the* *22 same time, or was there a different time?* *23 A There wasn't a decision in time, but* *24 the last procedures I did were just the suburethral* *25 slings and not the repair of the prolapse.* *22* *1 Q Was there any other reason that you* *2 stopped using mesh for pelvic organ repairs other* *3 than patient concerns?* *4 A Well, with all of the bad press I* *5 just felt like I would refer those patients for* *6 someone else to deal with.* *7 Q Would it be accurate to say that your* *8 decision to stop using mesh for pelvic organ* *9 prolapse repairs was not based on any experience you* *10 had with the mesh in your clinical experience?* *11 A No. I had some complications with* *12 mesh. I think anyone who did any volume of surgery* *13 would have had some, and you have complications when*

		14 you don't use it, complications most often being *15 recurrence.* *cc101714, (Page 23:20 to 23:25)* *23* *20 Q When do you think the last time was* *21 before your retirement that you used a Boston* *22 Scientific Uphold?* *23 A Probably a couple of years.* *24 Q That be approximately 2012?* *25 A I guess.*
cc101714, (Pages 28:5 to 29:14) 28 5 A Infrequently. 6 Q Did you notice any difference in your 7 patients experiencing complications between the 8 different products that you used? 9 A No. 10 Q In 2010 when Ms. Winebarger had her 11 surgery, what were you telling your patients about 12 the risks and benefits of using mesh for pelvic 13 organ prolapse repair? 14 A Well, I would tell them that -- that 15 it increased the likelihood of success of the repair. 16 That's not a risk, but I mean I'm just going to 17 through it -- 18 Q I asked for risks and benefits, yeah. 19 A And that the degree or the amount of 20 repair needed also increased the benefit -- I don't 21 think I said that clearly, but that if they were 22 dropped down more, it helped more. And that the risk 23 was pain. The risk was that -- that it could -- I 24 didn't use the word erosion usually with patients. I 25 would say that it could wear through to the surface 29 1 and possibly require additional surgery. I'd tell 2 them that sometimes there could be leakage 3 afterwards. And retention, 'cause you can get it too		*cc101714, (Page 29:15 to 29:18)* *29* *15 Q So the native tissue repair would* *16 also have risks associated with pain, urine leakage* *17 and retention, infection, and recurrence?* *18 A Not so much infection.*

4 tight. And infection, I would always mention 5 infection. 6 Q Other than the risks of -- I think as 7 you described it, the mesh wearing through -- 8 A Um-hmm. 9 Q -- were any of the other risks that 10 you just gave me specific to a repair with mesh as 11 opposed to a native tissue repair for pelvic organ 12 prolapse? 13 A It's not one versus the other. The 14 risks are present for both.		
cc101714, (Pages 32:19 to 33:2) 32 19 Q Do you understand -- do you 20 understand that the FDA reviews the language that's 21 in the directions for use in medical devices? 22 A Yes. 23 Q Are there any risks or potential 24 complications that you saw in your review of the DFU 25 for the Uphold that you were not aware of at the 33 1 time of Mrs. Winebarger's surgery? 2 A No.	32:19-33:2 FRE 401, 402, 403 FDA reference	
cc101714, (Pages 45:22 to 47:6) 45 22 Q In the weeks following her surgery 23 did you see Mrs. Winebarger? 24 A I saw her in the hospital until she 25 was discharged, and then I saw her back in the office 46 1 on August 30th, 2010. 2 Q At the time Mrs. Winebarger was 3 discharged were you pleased with her surgery? 4 A Yes. 5 Q At the time she was discharged did 6 you consider her surgery to be a success? 7 A Yes. 8 Q Was there anything unusual about 9 Mrs. Winebarger's immediate postoperative course? 10 A No. 11 Q Did you continue to follow 12 Mrs. Winebarger after her initial postop visit? 13 A She had a second postop visit, and 14 then that was the last time I had seen her, and the		

second visit was on October 27th, 2010. Q As of October 2010 was Mrs. Winebarger having any problems during her postoperative period? A She had mild urinary incontinence. Stress urinary incontinence. Q And was that a risk of the procedure she underwent? A Is that -- Q Is that a risk of the procedure she underwent? 47 A Yes. Q Would that have been a risk whether or not mesh was used? A Yes. Q Do you agree that Mrs. Winebarger benefitted from your surgery?		
cc101714, (Page 47:8 to 47:16) 47 A At the time I last saw her she seemed to. Q Have you ever concluded that mesh injured Mrs. Winebarger in any way? A No. Q Dr. Coryell, are you aware that for a device to be sold in the United States, it must be cleared by the Food and Drug Administration? A Yes.	47:5-16 FRE 401, 402, 403 FDA Reference	
cc101714, (Pages 48:24 to 49:7) 48 A Not that I recall. Q Did you rely on any sales 49 representatives in making medical decisions about the safety of the medical devices you used? A I would not say I relied on it, but it's part of the information I receive. Q Do you recall any Boston Scientific sales representative providing you with any information regarding the Uphold?		*cc101714, (Pages 79:9 to 80:8)* *79* *Q Earlier in today's deposition you were asked some questions about sales reps, and I believe you testified something to the effect that there were sales reps coming in, discussing pore size and the type of mesh. Do you recall that testimony?* *MS. BRATHWAITE: Objection.* *A Yes.* *Q What are some of the differences between these types of devices?*

		19 A With regards to anything in *20 particular, or just --* *21 Q I'm interested in the particulars.* *22 A My question was what particulars, I* *23 guess.* *24 Q Is pore size something --* *25 A Pore size? Pore size is something* *80* *1 that the various reps would talk about, and I would* *2 say that -- that the size could affect how well it* *3 was -- the tissue would grow into it to secure it.* *4 That small, too small of a pore size was not good.* *5 Q So it's your understanding then that* *6 pore size is a variable between these different* *7 types of pelvic organ prolapse products?* *8 A It's one of the variables.*
cc101714, (Page 51:21 to 51:23) 51 21 Q Of course. As part of your treatment 22 did you ultimately choose the Uphold to treat 23 Mrs. Winebarger's pelvic organ prolapse?	51:21-23;52:5 FRE 401, 402, 403, Foundation	
cc101714, (Page 52:5 to 52:9) 52 5 A Yes. 6 Q At the time of Mrs. Winebarger's 7 surgery did you have adequate information on how to 8 use the Uphold to properly perform the procedure? 9 A Yes.	52:6-9 FRE 401, 402, 403, Foundation, Legal Conclusion	
cc101714, (Page 52:11 to 52:13) 52 11 Q And similarly did you have adequate 12 information to properly evaluate the risks and 13 benefits of the Uphold for Mrs. Winebarger?	52:11-15 FRE 401, 402, 403, Foundation, Legal Conclusion	
cc101714, (Pages 52:15 to 53:1)		

52 15 A Yes. 16 Q Regarding the benefits, did 17 Mrs. Winebarger have the potential to benefit from 18 Uphold in the accompanying surgery you performed? 19 A Did she have the -- 20 Q The potential to benefit from the use 21 of Uphold in the accompanying surgery you performed? 22 A Yes. 23 Q At the time of Mrs. Winebarger's 24 surgery were you aware of all the risks included in 25 the Uphold DFU that we marked earlier? 53 1 A Yes.		
cc101714, (Page 53:3 to 53:6) 53 3 Q And specifically at the time of 4 Mrs. Winebarger's surgery in August 2010, were you 5 aware of the risks of pain, stress urinary 6 incontinence, recurrence, and erosion?		
cc101714, (Pages 53:8 to 54:16) 53 8 A Yes. 9 Q And based on the customary surgical 10 discussion that we discussed earlier, do you believe 11 you relayed these risks to Mrs. Winebarger before 12 her procedure? 13 A Yes. 14 Q Based on your clinical experience, do 15 you believe that Mrs. Winebarger was an appropriate 16 candidate for the Uphold? 17 A Yes. 18 Q Do you have any criticisms of the 19 warnings or the directions for use that we looked at 20 earlier? 21 A No. 22 Q Do you have any criticisms of the 23 performance of the Uphold based on your experience? 24 A No. 25 Q Do you -- back when you were 54	53:18 – 24 FRE 401, 402, 403	

practicing, did you consider mesh products available on the market for the treatment of pelvic organ prolapse to be a beneficial development to your practice and for your patients? A Yes. Q Doctor, do you rely on the FDA to do its job as part of -- sorry, strike that. Sorry. Doctor, are you aware that the Uphold at the time you were using it was a device that was only available through a licensed physician? A Yes. Q And as a device manufacturer, were you aware that part of the regulatory rules and regulations required Boston Scientific to make a showing to the FDA on the safety and effectiveness of its devices?	54:6-16; 402, 402, 403, Foundation, Misleading FDA Reference	
cc101714, (Page 54:18 to 54:24) 54 A Not specifically for Boston Scientific, but that's just something that they do for anything they approve. Q And as a doctor do you rely on the FDA to require a showing of the safety and effectiveness of a device before the FDA approves it?	54:18-24 FRE 401, 402, 403, Foundation Misleading FDA Reference	
cc101714, (Page 55:1 to 55:4) 55 A Yes. Q Do you understand that the FDA cleared the product that you implanted in Mrs. Winebarger?	55:1-55:4 FRE 401, 402, 403 Foundation, Misleading FDA Reference	
cc101714, (Page 55:6 to 55:6) 55 THE WITNESS: Yes	55:6 FRE 401, 402, 403 FDA Reference	
cc101714, (Page 70:2 to 70:4) 70 Q Did any Boston Scientific sales reps ever scrub in to surgeries you were performing? A No.	70:2-4 FRE 401	
cc101714, (Pages 72:10 to 73:14) 72 What are the mesh extensions secured to in the patient? A The sacrospinous ligament.		

13 Q And to secure the mesh extension to 14 the sacrospinous ligament, is it necessary to pass 15 through muscle tissue in the pelvic floor? 16 A It's not muscle, it's ligamentous 17 tissue. 18 Q And are these -- is this ligamentous 19 tissue in proximity to nerves running through the 20 pelvic floor? 21 A It -- yes. 22 Q Are there any major nerves extending 23 throughout the anatomy of the pelvic floor that the 24 mesh extensions would be in proximity to when you go 25 in to anchor them to the sacrospinous ligament? 73 1 A The nerves are there, but you avoid 2 them by your positioning of the device. 3 Q So am I correct that when you're 4 placing the mesh extensions in the sacrospinous 5 ligament, you take care to avoid any major nerves in 6 the pelvic floor? 7 A You don't actually see the nerves, 8 you just know where they are. 9 Q And that's because -- 10 A Because of anatomy. 11 Q -- of your experience with the pelvic 12 anatomy and your training and skills as a urologist; 13 correct? 14 A Right.		
cc101714, (Page 73:18 to 73:22) 73 18 Q Is it possible for the arms of this 19 mesh to contract post implantation, thereby 20 impinging on a nerve that was previously avoided 21 during the actual implant procedure itself? 22 A I would say it's unlikely.		*cc101714, (Page 73:15 to 73:17)* *73* *15 Q Doctor, are you familiar with the* *16 phenomenon known as mesh contraction?* *17 A I know what you're referring to* cc101714, (Pages 80:24 to 81:4) *80* *24 Q Is the amount of contraction that was* *25 anticipated something that varied between these*

		81 *1 products?* *2 A The amount of contraction may or may* *3 not have varied, but if it did, how much it did was* *4 not something that I was aware of.*
cc101714, (Pages 75:22 to 76:14) 75 22 Q Is it fair to say that the nerve runs 23 to the inside of where the sacrospinous ligament 24 runs within the pelvic floor? 25 A The nerve is kind of perpendicular 76 1 to -- not quite perpendicular, but relatively 2 perpendicular to the ligament. The ligament crosses 3 in front of it from where you are doing the surgery, 4 and then you place your -- the arm of the device to 5 the side of where it crosses there. So if the device 6 tightens it would tighten parallel or relatively 7 parallel to the nerve, not crossing the nerve. Does 8 that make sense, or do you understand what I mean? 9 Q Let me clarify it. So is it possible 10 for mesh contraction to cause the sacrospinous 11 ligament to impinge on this nerve you were just 12 describing? 13 MS. BRATHWAITE: Objection. 14 THE WITNESS: No.		*cc101714, (Pages 76:20 to 77:5)* *76* *20 Q Are there other nerves in the pelvic* *21 floor that mesh contraction could bring the* *22 sacrospinous ligament into proximity with?* *23 A There's nerve supply throughout the* *24 pelvic floor, but as far as specific nerves, not that* *25 I'm aware of.* *77* *1 Q So would I be correct in saying that* *2 mesh contraction could bring the sacrospinous* *3 ligament into contact with minor nerves throughout* *4 the pelvic floor, not the main nerves then?* *5 A I suppose.*
cc101714, (Pages 89:10 to 90:10) 89 10 Q Is the bad press that you were 11 referring to the July 2011 FDA alert and the -- the 12 ensuing aftermath? 13 MS. BRATHWAITE: Objection. 14 A Well, I was referring more to how 15 much you could see on TV saying don't get pelvic 16 mesh. 17 Q And I believe you testified earlier 18 that your patients had concern about the pelvic 19 mesh. 20 A Yes. 21 Q Did you share their concerns?	89:10-90:10 FRE 401, 402, 403 Post Implantation	

22 A Not to the degree that they had them. 23 Q What were your concerns when you 24 began seeing these -- these ads on TV and patients 25 began expressing concerns to you? 90 1 A The risks I don't think had really 2 changed; the risks were the risks. But how patient 3 satisfaction with their results had changed as a 4 result of this, because you can have pain whether you 5 use mesh or don't use mesh. You can have recurrence 6 whether you use mesh or don't use mesh. And so then 7 if you have any of those things you blame it on the 8 mesh. It's not necessarily because of the mesh. And 9 it's hard, I think, to determine whether or not it is 10 caused by the mesh or just the risks of the surgery.		
cc101714, (Pages 108:3 to 109:15) 108 3 Q I have a couple of follow-up ones, 4 Dr. Coryell. Very briefly talking about the 5 material safety data sheet. Let me mark our next 6 exhibit. I think we're on 8. 7 (Exhibit 8 was marked.) 8 Q Dr. Coryell, do you see the FDA's 9 question to Boston Scientific at the top of Exhibit 10 A? 11 A Yes. 12 Q And is this question specific to the 13 language that Mr. Casperson just showed you 14 regarding the medical application caution? 15 A Yes. It appears to be. 16 Q And underneath the background header 17 of this document, do you see where it says that 18 polypropylene homopolymer resin has been used by 19 Boston Scientific for permanent implant since the 20 late 1990's? 21 A Yes. 22 Q And this document goes on to explain 23 more background. The last sentence above the 24 section that says safety testing.	108:3-109:15 FRE 401, 402, 403 FDA Reference	

25 A Um-hmm. Yes. 109 1 Q Do you see where it says, "Boston 2 Scientific has performed extensive testing to 3 support the material is safe for use as a long term, 4 permanent implant device?" 5 A This? 6 Q Yes. 7 A Yes. 8 Q And I'm not going to ask you to study 9 this document here, but if you look at the next 10 pages, does it go into more detail about the studies 11 that Boston Scientific has done? 12 A Yes. 13 Q And do you rely on the FDA to 14 evaluate the composition of medical devices, or is 15 that something that you take on yourself?		
cc101714, (Pages 109:17 to 111:23) 109 17 A I rely on the FDA. 18 Q Have you ever relied on an MSDS for 19 any medical device as a basis for your medical 20 decision making? 21 A No. ***	109:17-21 FRE 401, 402, 403 FDA Reference	

1. **Objections to Exhibits**
   a. Plaintiffs object to Coryell Exhibit 8 under FRE 401, 402, and 403 as an impermissible FDA reference.

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 26, 2015, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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